UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
ENFORCEMENT AND
COMPLIANCE ASSURANCE

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**Subject:** Draft Programmatic Environmental Impact Statement - Introduction of Genetically Engineered Organisms , July 2007

Dear Dr. Wach:

In accordance with our responsibilities under Section 309 of the Clean Air Act and [the National Environmental Policy Act (NEPA)], the U.S. Environmental Protection Agency (EPA) has reviewed the U.S. Department of Agriculture's (USDA) draft programmatic environmental impact statement (DPEIS) for the *"Introduction of Genetically Engineered Organisms"*.

The USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for regulating the introduction (importation, interstate movement, and environmental release) of genetically engineered (GE) organisms that are known to, or could, pose a plant-pest risk (7 CFR Part 340). APHIS has prepared the DPEIS to evaluate the environmental impacts associated with revisions it is considering to its biotechnology regulations for GE organisms. This DPEIS analyzes the potential environmental issues resulting from APHIS' current regulations and any revisions or changes to APHIS' current regulations for GE organisms.

One purpose of revising the regulations would be to address current and future technological trends resulting in GE plants with which APHIS is less familiar (*e.g.*, plants engineered for environmental stress tolerance, plants engineered for enhanced nutrition, and plants engineered for new purposes such as biofuels, or production of pharmaceutical or industrial compounds). The revised regulations would ensure the following: 1) a high level of environmental protection; 2) a transparent regulatory process for stakeholders and the public; 3) a level of oversight commensurate with the risk; and 4) conformity with obligations under international treaties and agreements (*i.e.*, World Trade Organization (WTO) and the Cartagena Protocol on Biosafety (CPB)).

APHIS used an "Issues" approach to analyze the environmental impacts of its current regulations and any revisions. In this regard, APHIS formulated 11 broad categories of questions. Through a series of scoping meetings and surveys, these 11 categories were narrowed down to 10 Issues. For each Issue, several alternatives were proposed from which one alternative, (*i.e., the action decision*), was selected as the preferred action APHIS will use in its regulatory revision.

Various EPA offices have reviewed preliminary versions of this document, and appreciate APHIS' responsiveness in incorporating comments from these earlier reviews. As this DPEIS received wider distribution throughout EPA's Regional offices, additional comments were generated and concerns arose on some of the alternatives that were proposed for each Issue.

EPA concurs with APHIS' decision to revise its regulations at 7 CFR Part 340, and the preferred action specific to Issues 1, 2, 6, 7, and 8. We have identified additional information, data and/or the need for further analyses regarding the proposed alternatives for Issues 3, 4, 5, 9 and 10. We recommend this information be included in the Final PEIS. Specifically, our concerns center on the following:

**Issue 3 -** Granting Nonregulated Status. EPA recommends that APHIS consider a third alternative for Issue 3, to not deregulate any products.

**Issue 4 -** Permit Conditions for GMOs . EPA recommends that the alternatives proposed for this Issue analyze the human health and environmental impacts that could result from the inadvertent entry to the food supply of a "toxic" pharmaceutical or industrial compound that is produced in a food crop. The analysis should also address food safety concerns.

**Issue 5 -** Nonviable GE Material. EPA believes Alternative 3, to regulate all nonviable GE plant material should be the preferred action.

**Issue 9 -** Interstate Movement of Low-Risk Organisms. EPA recommends that the alternatives proposed for this Issue provide detailed criteria or definitions, on several terms, that would enable the reader to determine how permissive or restrictive APHIS will be when considering this topic, or to predict the potential environmental and human health impacts related to this Issue.

**Issue 10 -** Shipping Standards. EPA believes Alternative 3, expand the approved containers list and issue variances, should be the preferred alternative.

The enclosure presents detailed comments and, where appropriate, provides recommendations for improving the document's discussion of impact analysis and assessment of alternatives and the addition of clarifying language or information.

In light of our concerns about certain aspects of the DEIS, EPA has rated it as "Environmental Concerns-Insufficient Information" (EC-2), (see enclosed "Summary of Rating Definitions").

We appreciate the opportunity to review this Draft PEIS, and will continue to work with APHIS to resolve these issues in preparation of the Final PEIS. If you have any questions, please contact me at (202) 564-2400 or Arthur Totten, the staff contact for this project at (202) 564-7164.

Sincerely,

Anne Norton Miller
Director
Office of Federal Activities

Enclosures

cc: Janet Anderson, OPPTS
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# ENCLOSURE

## EPA DETAILED COMMENTS ON THE DRAFT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT *INTRODUCTION OF GENETICALLY ENGINEERED ORGANISMS*

## COMMENTS RELATED TO ALTERNATIVES ANALYSIS

The following comments discuss the analysis of the alternatives evaluated in the document for Issues 3, 4, 5, 9 and 10.

### *Alternatives Related to Issue 3*

APHIS' preferred action, Alternative 2, is to fully deregulate or regulate with modification, organisms that present a minor risk. The two alternatives that were presented do not provide the deliberate approach that is required to avoid long term impacts. Accordingly, EPA recommends that APHIS consider a third alternative for Issue 3, to not deregulate any products and include a discussion of this in the Final PEIS.

In a related matter, APHIS' ability to take action against deregulated products could cause problems for EPA and perhaps FDA in being able to react as appropriate. As an example, the deregulation of StarLink corn made EPA's enforcement action against this product more difficult. However, the fact that APHIS had not deregulated Bt10, assisted EPA in its effective enforcement action on this product being in the market place when it was not registered by EPA.

### *Alternatives Related to Issue 4*

APHIS' preferred action, Alternative 2, is to allow continued use of food and feed crops for pharmaceutical and industrial compounds and the open air field testing of these plants. EPA believes Alternative 3 in Issue 4, to not allow field testing of crops producing substances not intended for food uses, should be the preferred action because it may be very difficult to completely keep trace amounts of pharmaceutical and/or industrial compounds out of the food supply.

Moreover, EPA recommends that the Final PEIS provide further analysis of the human health and environmental impacts of an inadvertent entry to the food supply of a "toxic" pharmaceutical or industrial compound that is produced in a food crop. The analysis should also address food safety concerns.

*Alternatives Related to Issue 5*

APHIS' preferred action, Alternative 2, is to regulate certain nonviable GE plant material. EPA believes Alternative 3 in Issue 5, to regulate all nonviable (*i.e., nonliving*) GE plant material, should be the preferred action because nonviable plant material can still contain extremely high concentrations of transgene products.

Before nonviable plant material becomes eligible for deregulation, several issues should be addressed: the amount of novel protein in the nonviable plant, the persistence of nonviable plant material in the environment, the material's mobility, the nonviable plant material's effects on soil flora and fauna, and perhaps other issues that might arise in the public forum concerning this issue.

*Alternatives Related to Issue 9*

APHIS' preferred action, Alternative 2, is to exempt a class of GE organisms considered "well-studied" or presenting little environmental risk from permit requirements for interstate movement. EPA believes Alternative 3 in Issue 9, the creation of a process to apply for an interstate movement exemption, should be the preferred action.

Additionally, EPA recommends that the Final PEIS provide further development of several terms relied upon in the alternatives analyses. For example, the alternatives analyses should define or provide criteria for terms such as "well understood" and "low-risk". It should also define or provide criteria for determining what applications constitute "extensive use" in research. Without detailed criteria or definitions, it will be difficult to foresee how permissive or restrictive APHIS will be when considering this topic, or to predict the potential environmental and human health impacts related to this regulation.

*Alternatives Related to Issue 10*

APHIS' preferred action, Alternative 2, is to have performance-based standards for all shipping containers. EPA believes Alternative 3 in Issue 10, expanding the approved containers list and issuing variances, should be the preferred action because it offers greater protection of human health and the environment than performance-based guidelines.

## GENERAL COMMENTS

We offer the following points of clarification on various segments of the DPEIS:

- *INSIDE TITLE PAGE:* **Third Full Note**: This currently reads "...All uses of pesticides must be registered by appropriate State or Federal agencies before they can be recommended". This should read: "...All uses of pesticides must be registered by appropriate State or Federal agencies." As the agency which registers pesticides, it would be inappropriate for EPA to "recommend" pesticides.

- *TABLE OF CONTENTS:* We note that several of the appendices, tables and figures are not listed in the Table of Contents (*e.g.,* Appendix G. Socioeconomic and Sociocultural Effects, Appendix H. References, Appendix I, Distribution Lists, Appendix J. Index., Page 112, Figure 4-1. Heterologous Encapsidation, Page 140, Table 4-2. Tiered Permit System for Environmental Releases of GE Plants, Page 175, and Table 4-3. Examples of Federal Regulation of Various Types of GE Plants by EPA, FDA, and USDA). We suggest these be added to assist the reader during review of the document.

- *EXECUTIVE SUMMARY:*

  **Page ii, Purpose and Need:** EPA recommends that the Final PEIS describe the obligations and standards of international treaties and agreements (*e.g.,* World Trade Organization (WTO)) that the revised regulations will conform with.

  **Page iv, Permits:** EPA recommends that the Final PEIS include a description of management protocols for the permit application process.

- *SECTION II - PROPOSED PROGRAM ALTERNATIVES:* **Page 17, Proposed Program Alternatives:** EPA recommends that the Final PEIS include a specific discussion of APHIS' role under the *Coordinated Framework for the Regulation of Biotechnology* (51 *Federal Register* (FR) 23302) and compare it to FDA and EPA to make it clear that APHIS will not duplicate other agencies missions.

- *SECTION IV – ENVIRONMENTAL CONSEQUENCES:* **Page 140, Table 4-2, Tiered Permit System for Environmental Releases of GE Plants,** under the **Permit Conditions** column heading**:** This currently reads for Type 3: "Inspections: Up to 5 annual inspections" and for Type 4: "Inspections: At least as often as Type 3 ." This language might be interpreted to mean 0 to 5 inspections. The language in the Final PEIS in the charts for Type 3 and Type 4 should read, "Inspections: A minimum number of annual inspections should be given."

- *APPENDIX G – SOCIOECONOMIC AND SOCIOLOGICAL EFFECTS:* **Environmental Justice: Page G-5, Third Full Paragraph:** This currently reads: "...to APHIS' knowledge, no scientifically substantiated human nutritional or allergenicity concerns, including concerns for children, have been identified with any of the GE crops currently on the market." It is unclear whether this statement also includes populations of senior citizens, tribal entities, small, resource-poor farmers or other populations with differential patterns of subsistence consumption. EPA recommends the Final PEIS clarify this statement with respect to this point.

# U.S. Environmental Protection Agency Rating System for Draft Environmental Impact Statements

## Definitions and Follow-Up Action*

### Environmental Impact of the Action

**LO - - Lack of Objections:** The Environmental Protection Agency (EPA) review has not identified any potential environmental impacts requiring substantive changes to the proposal. The review may have disclosed opportunities for application of mitigation measures that could be accomplished with no more than minor changes to the proposal.

**EC - - Environmental Concerns:** The EPA review has identified environmental impacts that should be avoided in order to fully protect the environment. Corrective measures may require changes to the preferred alternative or application of mitigation measures that can reduce these impacts.

**EO - - Environmental Objections:** The EPA review has identified significant environmental impacts that should be avoided in order to provide adequate protection for the environment. Corrective measures may require substantial changes to the preferred alternative or consideration of some other project alternative (including the no-action alternative or a new alternative). EPA intends to work with the lead agency to reduce these impacts.

**EU - - Environmentally Unsatisfactory:** The EPA review has identified adverse environmental impacts that are of sufficient magnitude that they are unsatisfactory from the standpoint of public health or welfare or environmental quality. EPA intends to work with the lead agency to reduce these impacts. If the potential unsatisfactory impacts are not corrected at the final EIS stage, this proposal will be recommended for referral to the Council on Environmental Quality (CEQ).

### Adequacy of the Impact Statement

**Category 1 - - Adequate:** EPA believes the draft EIS adequately sets forth the environmental impact(s) of the preferred alternative and those of the alternatives reasonably available to the project or action. No further analysis of data collection is necessary, but the reviewer may suggest the addition of clarifying language or information.

**Category 2 - - Insufficient Information:** The draft EIS does not contain sufficient information for EPA to fully assess environmental impacts that should be avoided in order to fully protect the environment, or the EPA reviewer has identified new, reasonably available alternatives that are within the spectrum of alternatives analyzed in the draft EIS, which could reduce the environmental impacts of the action. The identified additional information, data, analyses or discussion should be included in the final EIS.

**Category 3 - - Inadequate:** EPA does not believe that the draft EIS adequately assesses potentially significant environmental impacts of the action, or the EPA reviewer has identified new, reasonably available alternatives that are outside of the spectrum of alternatives analyzed in the draft EIS, which should be analyzed in order to reduce the potentially significant environmental impacts. EPA believes that the identified additional information, data, analyses, or discussions are of such a magnitude that they should have full public review at a draft stage. EPA does not believe that the draft EIS is adequate for the purposes of the National Environmental Policy Act and/or Section 309 review, and thus should be formally revised and made available for public comment in a supplemental or revised draft EIS. On the basis of the potential significant impacts involved, this proposal could be a candidate for referral to the CEQ.

* From EPA Manual 1640 Policy and Procedures for the Review of Federal Actions Impacting the Environment. February, 1987.